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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,221	07/27/2005	Christopher Robin Lowe	GJE7140	2605

23557 7590 10/04/2007

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EXAMINER
PETERSEN, CLARK D

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,221	LOWE ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The specification requires a brief description of the drawings, briefly describing each and every figure presented.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 8, and 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1, 3, 9-12, 14, 16, 19, 20, 23, 25-27, 31-33, and 35 of copending Application No. 10/520323. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose inventions with the same limitations. It is noted that instant claim 1 requires that the cell be immobilized, whereas claim 1 of copending 10/520323 requires that the cell is inhibited from attachment to the surface of the chamber. However that limitation does not exclude that the cell is immobilized on a bead that is then inhibited from attachment to the surface of the chamber. Therefore the claims, as recited, are overlapping. Furthermore, claims 1, 3, 9-12, 14, 16, 20, 23, 31, and 35 of 10/520323 all disclose a sensor based method/device that measures a product that results from the cell's growth, similar to instant claims 1 and 8. Claims 9 and 25-27 disclose a plurality of chambers, similar to instant claim 13. Claims 11, 12, 32 and 33 disclose that the sensor is optical or holographic, similar to instant claims 1, 7, 8, and 14. Claim 23 recites an inlet for adding medium, similar to instant claim 12.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeffrey et al (WO 99/29831, from Applicant's IDS filed 18 Feb 2005).

Jeffrey et al teach a sensor for detecting the presence of microorganisms. They teach a "sensor plate" comprising a growth medium-containing layer on which microorganisms are immobilized. Beneath the growth layer is a sensor layer, which changes color upon growth of the microorganisms (see p. 3, lines 7-27, for example). The sensor layer can detect metabolites associated with growth (see p. 9, lines 6-14, for example). The cell can be a bacterial cell (see p. 9, lines 29-33, for example).

Therefore the teachings of Jeffrey et al are deemed to anticipate instant claims 1, 4, 5, 8, and 12.

Claims 1, 4, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Walt et al (US 6,377,721 B1, issued 23 April 2002).

Walt et al teach a method of monitoring cells by immobilizing them in a chamber, adding growth medium and a compound that fluoresces in response to a cell's metabolism (see Abstract; see col. 16 line 48 to col. 17 line 12, as examples).

Therefore the teachings of Walt et al are deemed to anticipate instant claims 1, 4, and 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-6, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeffrey et al in view of Benjamin et al (US 5,491,068, issued 13 Feb 1996).

The teachings of Jeffrey et al are discussed above and applied as before.

Jeffrey et al do not teach that cells are immobilized by antibody binding to magnetic beads.

Benjamin et al teach that one can concentrate bacteria from unknown samples by mixing the samples with magnetic beads on which bacteria-specific antibodies are immobilized. The beads (with bacteria attached) can then be directly transferred to a growth medium for colony growth. The bacteria can be of various pathogenic types, including those recited in instant claim 5 (see claims 1, 8, and 9, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to detect pathogenic bacteria by trapping them on magnetic beads with antibodies, followed by culture, and then detecting their presence with an optical sensor, because Benjamin et al teach that one can trap

bacteria on magnetic beads and then directly culture them on a solid medium, and Jeffrey et al teach that bacteria cultured on a solid medium containing a "sensor plate" will change color in response to bacterial metabolites, allowing an observer to determine the presence of viable, pathogenic bacteria.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to trap pathogenic bacteria with antibody-coated beads, culture them with a chromogenic medium, and observe color changes to confirm their presence.

Claims 1, 2, 4, 6, 8-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (US 6,377,721 B1).

The teachings of Walt et al are discussed above and applied as before. Additionally, Walt et al teach that cells can be immobilized in a well to which growth medium is added and cell metabolism is monitored; the means by which they can be immobilized can be antibody binding (see col. 13 line 46 to col. 14 line 4, for example). They also teach that the cells can be immobilized by magnetic means (see column 12, lines 55-64, for example). Walt et al also teach multiple chambers in a single device (see Abstract for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to bind cells in a growth chamber (microwell) with antibodies or by magnetic entrapment because Walt et al expressly claim a biosensor for measuring cell metabolism by means of fluorescence activated by

excitation light and detected by a fiber optic sensor, and they suggest that cells may be immobilized by antibodies or by magnetic means.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have a multichamber device in which cells are immobilized magnetically and/or by immunobinding, and are then interrogated optically to determine growth patterns.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Walt et al (US 6,377,721 B1), in view of Weimer et al (US 6,399,317, issued 4 June 2002) and in view of Lowe et al (US 5,989,923).

The applied reference (Lowe et al) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be

overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Benjamin et al are discussed above and applied as before.

Additionally Benjamin et al teach that bacteria isolated by means of antibody-coated magnetic beads can be grown in liquid medium (see col. 7, lines 30-35, for example).

Benjamin et al do not teach a device suitable for immobilizing a cell that also contains a sensor and a growth medium.

Benjamin et al do not teach a series of chambers.

Benjamin et al do not teach that the sensor is a holographic detector.

As discussed above, Walt et al teach that cells can be immobilized in a well to which growth medium is added and cell metabolism is monitored. Walt et al also teach multiple chambers in a single device (see Abstract for example). They also teach that the cells can be immobilized by immunophilic and magnetic means (see column 12, lines 55-64, for example), and that cell metabolism can be monitored by provision of a fluorescent metabolite, that fluorophores responsive to the metabolite can be activated by excitation light, and resulting fluorescence can be detected by fiber optics (see col. 15, lines 48-54, for example).

Weimer et al teach a device for detecting bacteria. The device contains beads which are coated with an antibody specific for a type of bacteria; these

beads can be magnetic. A sample suspected of containing bacteria is added through an inlet port, and allowed to flow through a chamber containing the beads. The beads then selectively accumulate bacteria from the liquid sample (see col. 3 line 40 to col. 4 line 19; see col. 6 lines 13-21, as examples). The bacteria can also be subsequently washed while bound to the magnetic beads by addition of a wash buffer (see Example 13, for example). Weimer teaches bacterial spores can be used to generate antibodies in mice. These antibodies can also be attached to beads, and will effectively capture spores in the chamber discussed above (see Examples 2, 3, and 13).

Lowe et al teach a holographic detector for measuring analytes. In particular the sensor has applications in detecting biologically secreted proteins or proteases. The inventors teach that the sensor is capable of detecting bacteria, for example (see col. 11, lines 18-46, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to detect bacteria by trapping them on beads with antibodies and detect their presence by means of a holographic sensor because Benjamin teaches that bacteria can be trapped on magnetic beads by means of antibodies and that they can subsequently be cultured in liquid media, Walt et al teach a biosensor in which immobilized cells are interrogated with a light source and optically measured, Weimer et al teaches that cells attached to beads can be washed in a buffer solution, and Lowe et al teach that holographic sensors make good sensors for optically interrogating bacteria.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide a device in which one can capture bacteria on immunomagnetic beads, provide them a growth medium, and observe their metabolism via optical interrogation with a holographic sensor.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
9/26/2007

JON WEBER
SUPERVISORY PATENT EXAMINER